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EXAMINER	
WEBB, WALTER E	

ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,801	GHOSAL, SHIBNATH	
	Examiner	Art Unit	
	WALTER E. WEBB	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6,7,9-11,13-16,22,24-30,33-36 and 38* is/are pending in the application.

4a) Of the above claim(s) *28,29 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6,7,9-11,13-16,22,24-27,30,33,34,36 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 10/6/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102--previous

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 9-11, 13-16, 22, 24, 25, 27, 30, 33, 34, 36 and 38 remain rejected under 35 U.S.C. 102(b) as being anticipated by Rowland (US 5,405,613) as evidenced by Ghosal (US 6,440,436), Janjua (infra) and Ghosal (US 6,124,268).

Rowland teaches a composition comprising Shilajit or an extract thereof in a vitamin and/or mineral preparation (see Abstract). The reference teaches that Shilajit is known for treating a number of diseases including diabetes (see col. 2, lines 1-10). Preferably, the Shilajit used in the reference is "Iron Shilajit", which is obtained by extracting raw Shilajit and treating it with a mixture of three herbs known as trifla, which includes *Emblica officinalis*, bahera and haritaki (see col. 4, lines 39-45). The purified Shilajit which is obtained is almost totally sterile (see col. 4, lines 45-48). The vitamin

preparation is taught to contain chromium at 10 to 80 micrograms as well as other vitamin such as vitamin A, C, D and E (see Table 1 at col. 10 and claim 2 at col. 14) **(claims 24, 25, 30, 34 and 38)**.

Shilajit inherently comprises oxygenated dibenzo-α-pyrones (DBP) and fulvic acids, as evidenced by Ghosal ('436) **(claims 14-16, 33 and 36)** (see col. 2, lines 23-28; see also Table 1 at col. 6). *Emblica officinalis* inherently comprises chromium and phenolic antioxidants, as evidenced by Janjua and Ghosal ('268) (see teaching below). Since Iron Shilajit is treated with *Emblica officinalis* it would inherently comprise a phenolic antioxidant-chromium complex.

Since the composition is taught to be mixed with chromium, it would inherently comprise DBP-chromium complexes, as well (see col. 3, lines 1-8).

In regard to claims 9 and 27, since the tannins come from the plant species instantly claimed, they would inherently have a molecular weight below 1000.

Claim Rejections - 35 USC § 103--previous

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1) Claims 1, 2, 9-11, 13 and 27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Janjua (Hamdard Medicus 1991) in view of Ghosal (US 6,124,268).

Janjua teaches that chromium is a compound that improves glucose tolerence in animals suffering from insulin disorder and is naturally found in *Phyllanthus emblica* (Amla fruit a.k.a. *Emblica officinalis*) (see first and second paragraphs at pg. 104). *Phyllanthus emblica* is taught to contain about 2.5µg/g of chromium (see table at pg. 105). The reference teaches that organic chromium salts are preferred for treating diabetes due to their being more acceptable to the body (see pg. 105, second parapraph).

As a plant species of the instant claims (claims 10 and 11), *Phyllanthus emblica,* which naturally contains chromium, would inherently comprise an antioxidant-chromium complex. It would also inherently comprise a low molecular weight hydrolyzable tannin having a molecular weight below 2000 or 1000, as per **claims 9 and 27**.

The reference differs from the instant claims insofar as it does not teach a purified tannin fraction of the plant species.

Ghosal teaches a method of purifying the tannin fraction of *Phyllanthus emblica* (see Example 1 at col. 6). Ghosal teaches an enriched natural antioxidative blend, which has advantageous antioxidant and free radical captodative properties (see col. 1, lines 9-16). Ghosal does not teach an antioxidant-chromium complex.

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to purify the antioxidant-chromium complex from *Phyllanthus emblica* for the purpose of treating diabetes, since Janjua teaches that *Phyllanthus emblica* is used medicinally for treating diabeties (see page 105, third paragraph) and organic chromium is more acceptable to the body. Furthermore, the artisan would have

been motivated to extract the organic chromium complex from the plant for use in various routes of adminitration, e.g. oral and parenteral. The artisan would have also been motivated to use the organic chromium complex of *Phyllanthus emblica* since the tannoids of the plant extract functions as therapeutic antioxidants, as evidenced by Ghosal.

2) Claims 6, 7, 22, 24, 25, 26, 30 and 34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Janjua and Ghosal as applied to claims 1, 2, 9-11, 13 and 27 above, and further in view of Riley et al. (EP 0037144 published October 7, 1981).

The combination Janjua and Ghosal does not teach the claimed specific chromium content in the complex or motivation for adding other active agents.

Riley et al. teaches stable chromium complexes for dietary supplementation for humans and lower animals, which are useful for treating diabetes (see Abstract). The reference teaches adding pharmaceutical excipients and carriers like sugars and oils (see pg. 9, lines 24-36). The reference teaches that the dosage of chromium complex will vary with the particular condition being treated (see pg. 8, lines 11-14). For example, single dosage amounts range from 0.15 to 100 micrograms of chromium per kg of body weight (see pg. 8, lines 14-19). The reference also teaches multivitamin/mineral compositions comprising vitamin A and C (**claims 24 and 25**).

Riley et al. does not teach a phenolic antioxidant-chromium complex.

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to adjust the amounts of the chromium in the composition of

Janjua to fall within the broad ranges of the instant composition since this is simply routine optimization. The artisan would have been motivated to add chromium for treating diabetes, since dosages tend to vary for persons being administered, as evidenced by Riley et al.

Generally, it is also *prima facie* obvious to select a known material based on its suitability for its intended use (see MPEP 2144.06). Thus, it would have also been obvious to add vitamins to the organic complex of Janjua based in their suitability for their intended use, as evidenced by Riley et al.

3) Claims 6, 7 and 26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Rowland (US 5,405,613) as applied to claims 1, 2, 9-11, 13-16, 22, 24, 25, 27, 30, 33, 34, 36 and 38 above, and further in view of Riley et al. (EP 0037144 published October 7, 1981).

Rowland differs from the instant claims 6 and 7 insofar as it does not teach a specific percentage of chromium content.

Riley et al. teaches stable chromium complexes for dietary supplementation for humans and lower animals, which are useful for treating diabetes (see Abstract). The reference teaches that the dosage of chromium complex will vary with the particular condition being treated (see pg. 8, lines 11-14). For example, single dosage amounts range from 0.15 to 100 micrograms of chromium per kg of body weight (see pg. 8, lines 14-19). The reference also teaches multivitamin/mineral compositions comprising vitamin A and C (**claims 24 and 25**).

Riley et al. does not teach a phenolic antioxidant-chromium complex.

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to adjust the amounts of the chromium in the composition of Roland to fall within the broad ranges of the instant composition since the composition would have been used to treat diabetes. The artisan would have been motivated to adjust the amount of chromium for treating diabetes, since dosages tend to vary for persons being administered, as evidenced by Riley et al.

Nonstatutory Obvious-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 14, 15, 22, 33 and 36 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 and 2 of Ghosal (US 6,440,436) and claim 1 and 7 of Ghosal (US 6,869,612).

The conflicting claims are not patentably distinct. Claim 1 of Ghosal (US 6,440,436) and claim 1 of Ghosal (US 6,869,612) are directed to the purified shilajit composition, which consists essentially of oxygenated dibenzo-a-pyrones in metal ion conjugate forms. Conjugates are known in the art to be joined or paired. A complex is known in the art as a combination of two or more compounds without covalent binding. As such, a complex can be view as a specific type of conjugate. The purified shilajit composition, which consists essentially of oxygenated dibenzo-a-pyrones in metal ion conjugate forms is the phenolic antioxidant-chromium complex of the instant claims. Thus the oxygenated dibenzo-a-pyrones in metal ion conjugate forms of Ghosal (US 6,440,436) and Ghosal (US 6,869,612) and the phenolic antioxidant-chromium complex of the instant application are obvious since chromium is a metal ion.

Response to Arguments

In regard to the 102 rejection applicant argues that Rowland is not anticipatory since it fails to teach a phenolic antioxidant-chromium complex in a purified tannin fraction of plant origin. Specifically, applicant states that the Examiner erred in concluding that extracted Shilajit "treated with" amla (emblica officianlis) means amla is added to the extracted Shilajit. Applicant argues that this conclusion is inconsistent with the rest of the wording of the paragraph, which adds that "purified Shilajit" is obtained.

Applicant states Rowland et al. would not obtain "purified Shilajit", since the addition of trifla and amla, by association, would be a contaminant. However, the reference teaches that the extracted Shilajit is treated with trifla "to remove possible contaminants." The very next sentence states, "The purified Shilajit which is obtained is then dehydrated to remove moisture." It appears that Shilajit is purified because of the addition of trifla.

Applicant attempts to offer an alternative definition for "treating" by stating that trifla could have been used as a fumigant e.g. burning the trifla "so as to produce smoke and directing the smoke to a container containing the Shilajit extract." However, this is not evidence, and there is no scientific basis for concluding that smoke can be used to remove contaminants in an extract. The artisan would undoubtedly treat the extract by adding trifla. Amla inherently comprises chromium and phenolic antioxidants, as evidenced by Janjua and Ghosal ('268). Since Iron Shilajit is treated with *Emblica officinalis* it would inherently comprise a phenolic antioxidant-chromium complex.

Furthermore, it is noted that the Rowland teaches mixing Shilajit, which itself comprises an antioxidant (DBP), with chromium. The composition would inherently comprise DBP-chromium complexes as well.

In regard to the 103 rejections, applicant argues that the Examiner has not provided information about how chromium and the antioxidant components are compartmentalized. However, it is not clear what applicant means by "compartmentalized." If Emblica officianalis has compartments the Examiner is unaware of it and no evidence has been presented describing it. What is clear is that Ghosal and

Janjua refer to and teach the contents of Emblica officinalis ***fruit***. Janjua teaches that the fruit naturally contains chromium, while Ghosal teaches that the fruit naturally contains antioxidants. Since the antioxidants and chromium are contained within the fruit, an antioxidant chromium complex would be inherent.

Applicant argues that the present invention provides unexpected results in the form of showing substantially improved effect when an external source of chromium is mixed with a phyllanthus emblica antioxidant fraction over phyllanthus emblica alone. Applicant refers to Example 4 of the specification as support for the unexpected results. The results at Table 1 show, in a diabetic mouse model, improved blood sugar lowering effect of the phylanthus emblica extract plus chromium over phylanthus emblica extract alone. However, since Janjua teaches administering phyllanthus emblica (Emblica officianalis) in combination with an external source of organic chromium to treat diabetes, applicant's results are not unexpected.

Even if applicant's data supported an unexpected result, the instant claims are not commensurate in scope with these results. For example, claim 1 generically recites a "phenolic-chromium complex", while Table 2 at page 30 of the specification shows use of Phyllanthus emblica extract plus Cr^{3+}, each at specific concentrations. Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results

occur over the entire claimed range. Here, the results are not shown to occur over the entire range of the generic claim.

Applicant also argues that secondary considerations in the form of long felt but unsolved need support the non-obviousness of the invention. Applicant states that this argument was previously made (see Arguments filed 11/27/2007, pg. 8, 4th paragraph). Specifically, applicant argues that the problem not solved by the prior art was chromium (III) converts to Chromium (IV) and induces delayed toxicity. Applicant supposes to solve this problem by combining chromium with an antioxidant. In regard to establishing a long felt need, MPEP 716.04 states that the claimed invention must satisfy a long-felt need which was recognized, persistent, and not solved by others. Applicant has not presented evidence that the problem was persistent and not solved by others. However, the prior art teaches using antioxidants to protect against toxicity caused by Chromium (III). Purely for the purpose of rebutting applicant's argument that the toxicity caused by chromium (III) was not solved by the prior art, the Examiner cites Burkhardt et al. (The International Journal of Biochemistry & Cell Biology 2001). Burkhardt et al. teaches that antioxidants such as melatonin, AFMK, resveratrol and uric acid, were able to reduce DNA damage (genotoxicity) induced by chromium III (see Abstract). Thus, applicant's invention fails to satisfy a long felt but unsolved need.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612